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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/856,944	07/16/2001	John Ernest Hart	GJE-68	6466

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EXAMINER

AFREMOVA, VERA

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 04/18/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/856,944

Applicant(s)
Hart

Examiner
Vera Afremova

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1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (e). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jan 28, 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 8, and 10-20 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 8, and 10-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

Status of claims

Claims 1-6, 8 and 10-20 as amended [Paper No. 9 filed 1/28/2003] are pending and under examination in the instant office action.

Claims 7 and 9 were canceled by applicant. [Preliminary amendment, paper No. 5 filed 7/16/2001].

Response to Arguments

Applicant's arguments filed 1/28/2003 [Paper No. 9] have been fully considered but they are not all found persuasive.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 8, and 15 as amended remain rejected under 35 U.S.C. 102(b) as being anticipated by Hart [IDS-AR] as explained in the prior office action and for the reasons below.

Claims are directed to a material having ability to reduce organ mass wherein material is "obtained" from ovarian venous blood, to a pharmaceutical composition with the material and to a method of administering the material to a patient in need of organ reduction.

The reference by Hart [IDS-AR] is relied upon as explained in the prior office action and repeated herein.

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Hart [IDS-AR] discloses clomiphene and a pharmaceutical composition with clomiphene which is having ability to reduce organ mass. It also teaches a method of administering clomiphene to a patient in need of organ reduction after hexoestrol treatment. The cited reference is considered to anticipate the claimed invention because both the cited and the claimed materials have an identical characteristic such as ability to reduce organ mass.

Applicant appears to argue (response page 6) that clomiphene is not a material which is “having ability to reduce organ mass” as required by the claimed invention. This is not found true in the light of the teaching of the cited reference which clearly discloses that “clomiphene administered alone decreased most of the organ weights”, for example: see page 192, last two lines.

Applicant’s argument as related to the source of the claimed material is not found persuasive for several reasons. First, the cited reference teaches that effects related to the organ weight can be produced by compounds either synthetic or natural, either steroidal or non-steroidal (page 186, line 3). The claimed material is not limited by nature, structure, weight or any other characteristics except “having ability to reduce organ mass”. The cited clomiphene is clearly a material which is “having ability to reduce organ mass”. Further, there is a reasonable belief^e that at least some amounts of clomiphene would be found in the animal blood or in the animal ovarian venous blood after administration of clomiphene, particularly at the high dose disclosed in the reference (fig. 1). Thus, the disclosed clomiphene is a material “having ability to reduce organ mass” and can be “obtained” from blood within the meaning of the claims. The

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claimed invention is a product-by-process and not a method of making the product. The applicant's composition is claimed as a product-by-process. Since the Patent and Trademark Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make comparisons therewith, a lesser burden of proof is required for the product-by-process claims because of their peculiar nature than when a product is claimed in the conventional manner. Thus, although the cited reference teaches administration of synthetic clomiphene and the cited reference does not disclose a method of purifying clomiphene from blood, the claimed invention is still considered to be anticipated by the cited reference within the meaning of the claims 1, 8 or 15.

Claim Rejections - 35 USC § 102/103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-5, 8, 10-13 and 15-19 as amended remain rejected under 35 U.S.C. 102(b) as anticipated by US 4,734,398 [A] or, in the alternative, under 35 U.S.C. 103(a) as obvious over US 4,734,398 [A] as explained in the prior office action and for the reasons below.

Claims 1-3, 8, 10, 11 and 15-17 are directed to a material having ability to reduce organ mass, to a pharmaceutical composition with the material and to a method for treating organ or tissue hypertrophy by administering the material to a patient in need of organ reduction wherein the material is "obtained" by collecting an ovarian venous blood of female mammal, preparing

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plasma from the ovarian venous blood, partially purifying the material from the plasma and obtaining fractions with molecular weights in the ranges 10-30 kD and/or 10-20 kD.

Claims 4, 5 12, 13, 18 and 19 are further drawn to a protocol of purifying the ovarian venous blood derived material having ability to reduce organ mass by steps of centrifuging blood plasma to obtain fractions with molecular weights ranges 10-30 kD and 10-20 kD, eluting fractions on an ion exchange column with gradient of 0-0.3 M NaCl, obtaining and dividing the eluted fractions.

The cited patent is relied as explained in the prior office action and repeated herein.

US 4,734,398 [A] discloses a material having ability to reduce organ mass (col. 3, line 55-58 or col. 10, lines 47, 61-64) which is obtained from ovarian venous blood of female mammal (col. 8, line 61), pharmaceutical compositions or test fractions with the material and a method for treating organ or tissue hypertrophy by administering the material to a patient in need of organ reduction (col. 9, lines 67-69 and col.10, lines 1-3). The material is obtained by steps of collecting an ovarian venous blood of female mammal (col. 8, line 63-65), preparing plasma from the ovarian venous blood by centrifugation (col. 9, lines 8, 18-19), partially purifying the material from the plasma by dialyzing with 10 kD exclusion membrane (col. 9, line 26), by chromatography and by washing with 0.5 M NaCl solutions (col. 9, lines 8-31). The patent teaches obtaining fractions with molecular weights in the ranges within 1-30 kD and/or 10-20 kD such as 12-15 kD, 14-18 kD, 22-25 kD which have capability of reducing organ mass or ovarian weight (col. 4, lines 19-21 and lines 27-31; col. 11, lines 52-54).

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The cited patent US 4,734,398 discloses material, composition with material and method of administering the material wherein the material and/or fractions appear to be identical to the presently claimed material since it was obtained from identical source such as ovarian venous blood of a mammal and it produces identical effect such as organ mass reduction when administered to a patient. The cited patent also teaches identical molecular weights or overlapping ranges of molecular weights of fractions having ability to reduce organ mass as the presently claimed fractions. Consequently, the claimed material, composition with material and method of administering the material appear to be anticipated by US 4,734,398.

In the alternative, even if the claimed material and/or fractions are not identical to the referenced material/fractions with regard to some unidentified characteristics related to the use of particular ion exchange chromatography columns or specific concentrations of NaCl, for example, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced material and/or fractions are likely to inherently possess the same characteristics of the claimed microorganism particularly in view of the similar characteristics which they have been shown to share such identical source, identical effects and identical molecular weights. Thus the claimed material, composition with material and method of administering the material would have been obvious to those skilled in the art within the meaning of USC 103. Accordingly, the claimed invention as a whole was at least prima facie obvious, if not anticipated by US 4,734,398, especially in the absence of evidence to the contrary.

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Applicant appears to argue that the material of the cited US 4,734,398 (di Zerega) is not characterized as “having ability to reduce organ mass” as required by the claimed invention because no data is disclosed as relating to general reduction of organ mass (response page 7, par. 3). This is not found true because the cited patent demonstrates a decrease in ovarian weight after administration of fractions derived from ovarian venous blood, for example: see col. 10, line 45-48. Applicant’s arguments as directed to co-administration of the cited fractions with gonadotrophins do not provide persuasive grounds because gonadotrophins are taught as being capable to induce ovarian regrowth and/or ovarian mass gain and because the fractions derived from ovarian venous blood are taught as inhibiting effects of gonadotrophins. Applicant also appears to argue that the claimed material is capable to reduce mass of heart or kidneys (page 8, lines 1-3). Yet, the claimed invention is not so limited. In addition, it appears that the reference material also has that “ability” since it decreases mass of other organs as taught therein. Thus, the cited patent teaches and/or suggests the identical effects such as reduction of organ mass of the fractions which are characterized by identical molecular weight and which are derived from identical source (ovarian venous blood) within the meaning of the claims.

Further, applicant appears to argue that the cited patent US 4,734,398 (di Zerega) neither teach nor suggest a material with effect similar to that is claimed which is “ability to reduce organ mass” as encompassed by the claimed invention and as argued (response pages 8-9). However, the cited patent teaches that fractions derived from ovarian venous blood are capable to inhibit effects of gonadotrophins which induce ovarian regrowth and weight increase. Thus, the

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fractions derived from ovarian venous blood of the cited patent are taught and/or suggested as having the same organ mass reduction effects as the effects of the claimed material regardless mechanism of action and/or interaction with other physiologically active compounds. The claimed invention is not limited to the treatment of specific organs or tissues, to the history of patient organ hypertrophy, if any, and/or to the "need(s)" of the patient under treatment to distinguish between physical and/or functional differences, if any, which might be intended for the claimed invention.

Claim Rejections - 35 USC § 103

Claims 1-6, 8 and 10-20 as amended remain rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,734,398 [A].

Claims 1-5, 8, 10-13 and 15-19 as explained above. Claims 6, 14 and 20 are further drawn to the use of sheep as source of mammalian ovarian venous blood for obtaining material having ability to reduce organ mass.

The cited patent is relied as explained in the prior office action and repeated herein.

US 4,734,398 [A] is relied upon as explained above. The particular example discloses humans as source of mammalian ovarian venous blood for obtaining material/fractions having ability to reduce organ mass. But the cited patent also teaches that these materials/fractions are proteins (col. 8, line 61 and col. 10, last line) and that the activity of proteins is interspecies and that it is both produced and effective in monotocous and polytocous mammals (col. 3, line 29).

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Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to obtain material/fractions having ability to reduce organ mass from various mammals including human and sheep with a reasonable expectation of success in obtaining proteins fractions effective for reducing organ mass or for treating organ or tissue hypertrophy because activity of similar proteins is interspecies and similar effective proteins are produced in monotocous mammals or mammals producing mainly one young such as humans, for example, and in polytocous mammals or mammals producing several youngs such as sheep, for example. One of skill in the art would have been motivated to use various mammals including sheep as the source of therapeutically valuable materials for the benefits of obtaining drugs suitable for reducing organ mass or for treating organ or tissue hypertrophy. Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary. The claimed subject matter fails to patentably distinguish over the state art as represented by the cited references. Therefore, the claims are properly rejected under 35 USC § 103.

No claims are allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (703) 308-9351. The examiner can normally be reached on Monday to Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vera Afremova

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April 14, 2003.


IRENE MARX
PRIMARY EXAMINER